

**REMARKS**

This amendment is responsive to the non-final Office Action issued November 3, 2009. Reconsideration and allowance of claims 1, 8, 9, 13, 29-22, 24, 25, and 27-36 are requested.

**The Office Action**

Claims 1-3, 7, 8, 13, 15, 18, and 20-25 stand rejected under 35 U.S.C. § 103 over Packer (US 6,557,695) as modified by Castro-Pareja (US 7,280,710) as further modified by either Fujii (US 5,285,786) or Yoshioka (US 6,859,548).

Claims 2, 3, 7, 8, 9, 13, 15, and 18-20 stand rejected under 35 U.S.C. § 112, second paragraph.

Claims 13, 19-21, and 23-26 stand rejected under 35 U.S.C. § 112, first paragraph.

**The Claims Distinguish Patentably  
Over the References of Record**

Claim 1 calls for combining the current image with only a section of the map image. As shown in Figure 1, in the combined image, the current image C is combined with only a small section 7 of the map image.

This is significant in a number of medical procedures, such as moving a catheter through the vasculature of a patient. The current image shows the current position of the catheter and the current image of the vasculature, i.e., the actual positions of the internal structures of the patient. The map images, by distinction, were previously generated and stored in a memory. The map images depict the normal or expected positions of the vasculature in various motion states but not the actual current positions. The catheter is not shown in the map images. In the example of moving a catheter through the vasculature, the current image may be taken, for example, by a C-arm x-ray device which generates a projection image which shows multiple layers of the vasculature superimposed and, because x-rays are in many ways less than ideal for imaging the vasculature, the vasculature may be difficult to distinguish. As the catheter advances through the vasculature, there are decision points where the vasculature branches and either of two routes may be taken. When

the current image is ambiguous due to multiple layers of the vasculature or weak difficult to distinguish vasculature, these decision points may be difficult to determine. Because the map image provides a map of the vasculature, the decision points are easy to see.

An advantage of combining only a small section of the map image with the current image is that the real-time current state of the patient is shown in the majority of the image. Yet, in a small region, such as the region adjacent the tip of the catheter in the above-example, the map image is combined with the current image which, in the above-example, provides easy-to-decipher upcoming decision points, even though the map image is not current.

Packer does not recognize or address this problem. Packer proposes a diametrically opposite approach. Specifically, Packer proposes to display the high resolution MRI image which, was again determined at a prior time and which do not show a position of a medical device. Packer proposes to take the two previously reconstructed MRI images which are closest to the current phase or state of the heart and interpolate them into an approximation of the current phase using an iterative process in which a cost function is minimized. The current location of the tip of the medical device is determined from the ultrasound image and a representation of the tip, such as icon, cursor, or cross-hairs is superimposed on the MRI image. Thus, rather than displaying the real-time or current image as required by claim 1, Packer displays the previously generated MRI image interpolated to approximate the current cardiac phase of the patient. This has the disadvantage that the surgeon moving the medical device cannot see what is happening currently or in real-time in the patient. Rather, the surgeon must believe that the interpolated previously-generated MRI images in fact are an accurate representation of the current positions of the various organs and the heart in the patient. Indeed, Packer does not display any part of the real-time image, but rather uses the ultrasound data to determine the current location of the medical device and overlay a representation of it on the interpolated previously-generated MRI image. In this manner, Packer loses the advantages of real-time or current images depicting what is happening currently within the patient.

Further regarding claim 1, it is submitted that column 10, lines 31-36 of Packer cited by the Examiner along with the preceding and following text do not

actually describe reconstructing an ultrasound image and combining such reconstructed ultrasound image with the MRI image. Rather, these paragraphs suggest that the ultrasound data is used more in the nature of distance gauging signals to determine the location of the ultrasound device, hence the medical device which carries it, relative to the heart wall. It is submitted that it is these relative distances that allow an icon or other representation of the medical device to be overlaid on the MRI image. Indeed, the ultrasound system of Packer is not described as and does not generate an image of the medical device which is carrying the ultrasound probe.

Neither Castro-Pareja, nor Fujii, nor Yoshioka were cited as and do not cure this shortcoming of Packer.

Claim 9 calls for a distance image in which each pixel is assigned a vector which indicates the direction or distance therefrom which has a greater probability of a presence of a spatially-defined structure. Neither Packer nor the teaching references disclose or fairly suggest a distance image.

Claim 8 calls for the processor to assign each pixel of the section of the map image a probability that it belongs to a spatially defined structure.

Packer operates on the MRI image using an iterative process in which a global minimum of a cost function is determined. There is no suggestion of determining a probability for each pixel of the MRI image that it belongs to a spatially defined structure, such as a heart wall, vessel, or the like. The teaching references were not cited as and do not cure this shortcoming of Packer.

New claim 27 focuses on using the device of claim 1 in conjunction with a catheter or guided wire moving through blood vessels of a patient and further defines the operations performed by the processor in this environment, such as using a distance image. Claims 28-30 further refine the operations performed by the processor. Accordingly, it is submitted that claims 27-30 define yet more forcefully over Packer and the other references of record.

Claim 13 has been amended to become a method claim. Because the computer-readable memory limitation has been eliminated, it is submitted that the 35 U.S.C. § 112, first paragraph rejection has been resolved.

Claim 13 further calls for combining the map image around the estimated position of the object with the current image. By contrast, Packer

interpolates the MRI map image to a current cardiac phase of the patient and superimposes an icon or other representation of the medical device on the map image.

Dependent claims 19, and 31-33 depend from and further modify claim 13 and, it is submitted, distinguish yet more forcefully over the references of record.

Claim 20 has been amended to address the 35 U.S.C. § 112, first paragraph rejection. Claim 20 calls for the processor to estimate the position of the object depicted in the current image in the map image. By contrast, in Packer, the ultrasound probe is carried by the medical device which causes the ultrasound data to represent a wall of the heart. Such ultrasound data does not include a representation of the medical device. Thus, the medical device of Packer is not depicted in a current, ultrasound image.

Claim 20 calls for combining the corresponding map image with the current image with the estimated position of the object in the corresponding map image superimposed on the detected position of the object in the received current image. Packer functions diametrically opposite. That is, Packer superimposed an icon or other representation of the medical device on the MRI image, which MRI image is not a current image.

Claims 21-25 and 34-36 dependent therefrom contain further limitations which distinguish the claims yet more forcefully over Packer and the other references of record. Accordingly, it is submitted that claims 20, 21-25, and 34-36 distinguish patentably and unobviously over the references of record.

#### **35 U.S.C. § 112, Second Paragraph**

The claims have been carefully amended to resolve the 35 U.S.C. § 112, second paragraph objections raised by the Examiner.

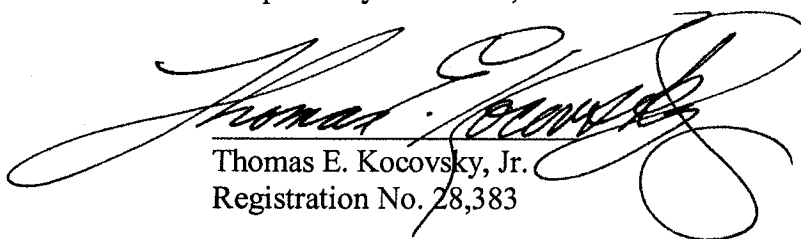
The specification has also been amended to address the Examiner's objections.

**CONCLUSION**

For the reasons set forth above, it is submitted that claims 1, 8, 9, 13, 29-22, 24, 25, and 27-36 distinguish patentably over the references of record and meet all statutory requirements. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, the Examiner is requested to telephone Thomas Kocovsky at 216.363.9000.

Respectfully submitted,



Thomas E. Kocovsky, Jr.  
Registration No. 28,383

FAY SHARPE LLP  
The Halle Building, 5th Floor  
1228 Euclid Avenue  
Cleveland, OH 44115-1843  
Telephone: 216.363.9000 (main)  
Telephone: 216.363.9122 (direct)  
Facsimile: 216.363.9001  
E-Mail: [tkocovsky@faysharpe.com](mailto:tkocovsky@faysharpe.com)

Direct All Correspondence to:  
Yan Glickberg, Reg. No. 51,742  
P.O. Box 3001  
Briarcliff Manor, NY 10510-8001  
(440) 483-3455 (tel)  
(440) 483-2452 (fax)